410 Rec'd PCT/PTO 17 SEP 1999

-FORM-PTO-1390 (Rev. 5-93) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER: 2426-1-001

U.S. APPLICATION NO. (If known, see 37 C.F.R. 1.5): 09/381561

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/GB98/00815	18 March 1998	19 March 1997

TITLE OF INVENTION: RECORDING ASSAY DEVICE

APPLICANT(S) FOR DO/EO/US: James Richard JACKSON

OIPE SEP 17 1999 PATENT & TRADEMARK OFFICE

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. [X] This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. [ ] This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. [X] This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and the PCT Articles 22 and 39(1).
4. [X] A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. [X] A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. [X] is transmitted herewith (required only if not transmitted by the International Bureau).
   b. [X] has been transmitted by the International Bureau.
   c. [ ] is not required, as the application was filed in the United States Receiving Office (RO/US)
6. [X] A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. [X] Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. [X] are transmitted herewith (required only if not transmitted by the International Bureau).
   b. [X] have been transmitted by the International Bureau.
   c. [ ] have not been made; however, the time limit for making such amendments has NOT expired.
   d. [ ] have not been made and will not be made.
8. [X] A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. [X] An executed oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. [ ] A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern other document(s) or information included:

11. [ ] An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. [ ] An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. [X] A FIRST preliminary amendment.
    [ ] A SECOND or SUBSEQUENT preliminary amendment.
14. [ ] A substitute specification.
15. [ ] A change of power of attorney and/or address letter.
16. [X] Other items or information:

SMALL ENTITY STATEMENT; TWO (2) SHEETS OF DRAWINGS; COPY OF INTERNATIONAL SEARCH REPORT; COPY OF NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT; COPY OF WRITTEN OPINION

EXPRESS MAIL "MAILING CERTIFICATE NO.": EL424845590US DATE OF DEPOSIT: SEPTEMBER 17, 1999

Rec'd PCT/PTO 17 SEP 1999

U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 09/381561	INTERNATIONAL APPLICATION NO PCT/GB98/00815	ATTORNEY'S DOCKET NUMBER 2426-1-001

17. ☒ The following fees are submitted:	CALCULATIONS	PTO USE ONLY
Basic National Fee (37 CFR 1.492(a)(1)-(5)):		
Search Report has been prepared by the EPO or JPO $840.00		
International preliminary examination fee paid to USPTO (37 CFR 1.482) $670.00		
No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2)) $760.00		
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO $970.00		
International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4) . . . . . $ 96.00		
ENTER APPROPRIATE BASIC FEE AMOUNT =	$ 840.00	
Surcharge of **$130.00** for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	$	

Claims	Number Filed	Number Extra	Rate		
Total Claims	19 -20 =	0	X $ 18.00	$ .00	
Independent Claims	1 -3 =	0	X $ 78.00	$ .00	
Multiple dependent claim(s) (if applicable)			+ $260.00	$ .00	
TOTAL OF ABOVE CALCULATIONS =				$ 840.00	
Reduction for 1/2 for filing by small entity, if applicable. Verified Small Entity statement must also be filed. (Note 37 CFR 1.9, 1.27, 1.28).				$ 420.00	
SUBTOTAL =				$ 420.00	
Processing fee of **$130.00** for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(f)). +				$	
TOTAL NATIONAL FEE =				$ 420.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). $40.00 per property +				$	
TOTAL FEES ENCLOSED =				$ 420.00	
				Amount to be: refunded	$
				charged	$

a. ☒ A check in the amount of $ 420.00 to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. 11-1153 in the amount of $_____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 11-1153. A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

DAVID A. JACKSON
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SIGNATURE

NAME

David A. Jackson

REGISTRATION NUMBER 26,742

EXPRESS MAIL "MAILING CERTIFICATE NO.": EL424845590US DATE OF DEPOSIT: SEPTEMBER 17, 1999

Patent
Attorney's Docket No. 2428-1-001

Applicant or Patentee: James Richard Jackson

Application or Patent No.: _____

Filed or Issued: _____

For: RECORDING ASSAY DEVICE

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 C.F.R. §§ 1.9(f) AND 1.27(b)) - INDEPENDENT INVENTOR

As a below-named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 C.F.R. § 1.9(c) for purposes of paying reduced fees under Sections 41(a) and 41(b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled RECORDING ASSAY DEVICE described in:

[X] the specification filed herewith
[ ] Application No. _____, filed _____
[ ] Patent No. _____, issued _____.

I have not assigned, granted, conveyed, or licensed and am under no obligation under contract or law to assign, grant, convey, or license any rights in the invention either to any person who could not be classified as an independent inventor under 37 C.F.R. § 1.9(c) if that person had made the invention, or to any concern that would not qualify as either a small business concern under 37 C.F.R. § 1.9(d) or a nonprofit organization under 37 C.F.R. § 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

[X] no such person, concern, or organization
[ ] persons, concerns, or organizations listed below*

*NOTE: Separate verified statements are required from each named person, concern, or organization having rights to the invention averring to their status as small entities. (37 C.F.R. § 1.27.)

FULL NAME _____

ADDRESS _____

[ ] individual [ ] small business concern [ ] nonprofit organization

FULL NAME _____

ADDRESS _____

[ ] individual [ ] small business concern [ ] nonprofit organization

FULL NAME _____

ADDRESS _____

[ ] individual [ ] small business concern [ ] nonprofit organization

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earlier of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 C.F.R. § 1.28(b).)

Attorney Docket No. 2426-1-001

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code; and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Name JAMES RICHARD JACKSON

Signature James Jackson Date 17 Sept 99

Name _____

Signature _____ Date _____

Name _____

Signature _____ Date _____

PATENT
2426-1-001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS : James Richard Jackson

APPLICATION NO. : PCT/GB98/00815

FILED : 18 March 1998

FOR : RECORDING ASSAY DEVICE

PRELIMINARY AMENDMENT

ASSISTANT COMMISSIONER FOR PATENTS
BOX PCT
WASHINGTON, D.C. 20231

Sir:

Prior to calculating the fees pursuant to the entry into the National Phase of the above-identified Application, please amend the claims as follows:

IN THE CLAIMS:

In Claim 3, line 1, delete "Claims 1 or 2" and insert --Claim 1--.

In Claim 4, line 1, delete "Claims 1-3" and insert --Claim 1--.

In Claim 5, line 1, delete "Claims 1-4" and insert --Claim 1--.

In Claim 6, line 1, delete "Claims 1-5" and insert --Claim 1--.

In Claim 7, line 1, delete "Claims 1-6" and insert --Claim 1--.

In Claim 9, line 1, delete "or 8".

In Claim 10, lines 1 and 2, delete "Claims 7-9" and insert --Claim 7--.

In Claim 11, line 1, delete "Claims 7-10" and insert --Claim 7--.

In Claim 13, line 1, delete "Claims 11 or 12" and insert --Claim 11--.

In Claim 16, line 1, delete "Claims 1-15" and insert --Claim 1--.

In Claim 17, line 1, delete "Claims 1-16" and insert --Claim 1--.

In Claim 18, line 3, delete "Claims 1-17" and insert --Claim 1--.

In Claim 19, line 1, delete "any preceding";

line 1, after "claim" insert --1--.

REMARKS

The above amendments are submitted herewith to reduce multiple dependencies and to conform the claims more closely to U.S. practice.

The amendments made herein are with respect to Claims 1-19 which were the claims amended during the pendency of the International Application. The amended claims were received by the International Office on May 10, 1999 and are included in the Notification of Transmittal of The International Preliminary Examination Report. A copy of the Notification, with the amended claims, is enclosed herewith for your reference.

PATENT
2426-1-001

Entry of the foregoing amendments and early and favorable processing in the National Phase before the United States Patent and Trademark Office is courteously solicited.

Respectfully submitted,

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2/PRTS

RECORDING ASSAY DEVICE

The invention herein described is an assay and recording means for use in, particularly but not exclusively, the diagnosis and/or analysis of tissue and/or fluid samples taken from a human or animal which comprises an assay part and a detachable data recording part.

The analysis of tissue or fluid samples is of crucial importance if the appropriate diagnosis of a patient is to be made by a healthcare worker. Also, there are numerous conditions that need constant monitoring to maintain the correct treatment regime. For example,and not by way of limitation, infectious disease (including HIV), diabetes, osteoporosis, tumour cell markers, reproductive endocrinology, thyroid disease haematology, therapeutic drugs, drugs of abuse, cardiac disease, treatment monitoring clinical trials assessment.

Also, it is apparent that the human genome project will identify genes that are involved, either directly or indirectly, in a number of inherited genetic diseases. Clearly it will be important to efficiently process this genetic information to offer appropriate treatment and/or counselling to individuals that are genetically predisposed to certain diseases. It is highly likely that both conventional processing facilities (i.e. to deal with monitoring various metabolites as described above) and also new means to efficiently process genetic information will be required to deal with expanding healthcare.

It is also apparent that there are situations where adequate medical advice/treatment is either unavailable or not easily accessible to individuals. For example, and not by way of limitation, armed forces personnel on active

service in war zones, armed forces personnel on active service in non-war situations but are effectively remote from medical assistance (i.e. ships, submarines etc), individuals that farm in remote areas (i.e. Australian outback, Africa), individuals who work for long periods away from adequate medical assistance (i.e. workers on oil/gas installations, research workers in polar or tropical regions, merchant navy personnel). It is important that these individuals receive rapid and reliable diagnosis of their condition so that the correct treatment is administered.

Also a number of the planets inhabitants live on remote islands that do not have extensive medical support and may require a rapid means to diagnose a condition that obviates the need for the individual to visit a mainland hospital or alternatively for a doctor to visit the individual on the island to remove samples for analysis.

On a less extreme note there are examples where, although a hospital is local to an individual, there may be extenuating circumstances that prevent or make difficult the attendance of the individual at an outpatients clinic to give samples for testing. Those suffering, for example, from bronchitis or emphysema, the elderly and infirm and any other individuals who would find a trip to their local hospital physically stressful and potentially hazardous. Currently, patients of this type can have home visits to monitor their condition. However, these are expensive and time consuming since some of a healthcare workers effective time is spent travelling to the patients home.

In addition it may be desirable to analyse the recorded result of an assay by a healthcare worker at a data processing site remote from the patient rather that rely on the patient to record and report the result of the test. There are

certain patients, (i.e. those suffering from mental disorders e.g. depression schizophrenia), where it may be desirable to keep the results of an assay secret until the healthcare worker can process the data to enable the correct diagnosis to be determined. It is well known in the art that patients can wilfully interfere with an assay to give an erroneous measure of the particular variable monitored by the assay. If the recording device merely records the information for subsequent processing and analysis this possibility is minimised.

This has particular relevance in clinical trial assessment of candidate drugs to provide a non-biased data collection means from treated and placebo groups to ensure a reliable assessment of drug efficacy is obtained.

It is therefore an object of the invention to provide a generic assay and a recording device which efficiently monitors an individuals health status.

It is a further object of the invention to provide an assay and recording means wherein said recording means is detachable from said assay means.

According to a first aspect of the invention there is provided an assessment device comprising an assay part and a recording part wherein said recording part is detachable from said assay part.

In a preferred embodiment of the invention said assessment device is selectively sized and shaped to facilitate handling and transport of the assessment device to the relevant processing facility.

In a preferred embodiment of the invention said recording device is selectively sized and shaped to facilitate handling and transport of the recording device to the relevant processing facility.

The above embodiment relates to a recording device that is sufficiently small and light to be transported via a conventional transport means for example, and not by way of limitation, the postal service or courier service.

In an alternative preferred embodiment of the invention said recording device may be adapted to facilitate data transfer via electronic means.

It will be apparent that in subsequent years the use of the Internet will become more widely accessible to the general public. The recording device may therefore be adapted to interface with a personal computer within an individuals home or place of work. Data transfer ideally will be encrypted to prevent third party access and decoded at a processing facility via responsible healthcare worker.

In yet a further preferred embodiment of the invention said detachable recording device is provided in retro-fit form, i.e. it may be desirable to adapt a pre-existing assay device to receive a recording part to enable data recording and storage.

It will be apparent from the above embodiment that the assessment device may be manufactured as a single unit. Alternatively, via suitable adaptation, said recording part or device may be attached to an existing assay part or device to enable data recording.

In yet a further preferred embodiment said recording device is a micro processor or other similar electronic device. Alternatively, said recording device is photographic, comprising, for example, a photographic emulsion, the stored images of which are developed at a processing facility.

It will be apparent that the above means for recording data from the assay can be processed by conventional means at the processing facility by down loading the stored information/images at a computer by a healthcare worker. Alternatively, if the worker has access to the internet the data/images can be transferred electronically from the individual to the healthcare worker at the processing facility.

In yet a further preferred embodiment of the invention there is provided an assessment device comprising an assay part with at least one sample application well.

Reference herein to sample application well is intended to encompass any recepticle, recess, indentation, or well into which a tissue/fluid sample can be placed.

Reference herein to a fluid sample is intended to include both a liquid and a gas sample, for example, urine, blood, saliva, mucous, pus, semen,breathe.

In a preferred embodiment of the invention said recording assay device is characterised by multiple sample application wells. Ideally, one or more of said well or wells is provided, suitably impregnated, with materials for sampling said fluid sample.

In yet a further preferred embodiment of the invention said assay part is adapted by the provision of at least one primary conduit in fluid connection with said sample application well. Ideally said primary conduit contains assay reagents in some instances suitable for diluting said sample fluid. More preferably further still, said conduit is suitably sized to facilitate capillary flow of said sample fluid therethrough.

In yet a further preferred embodiment of the invention said assay part is further adapted by the provision of at least one secondary conduit which is in fluid connection with one or more of said sample application wells; and which is ideally also adapted to provide for capillary flow therethrough. Preferably further still said secondary conduit contains assay reagents, ideally of a nature different to the assay reagents in said primary conduit but most suitably compatable therewith so as to provide, in total, for the complete and selected assaying of said fluid sample as it flows through either or both of said primary/ secondary conduits.

In yet a further preferred embodiment of the invention at least one control or calibration is provided in the assessing device. For example, a control conduit may be provided for monitoring flow through the device. Said control conduit may optionally be providedwith assay reagents, or alternatively, the elements, to be detected by the assay inorder to produce a positive result or identification.

In yet still a further preferred embodiment of the invention there is provided an assay part provided with at least one assay conduit which is further characterised by a detection zone to facilitate the detection of the product(s) of the assay.

According to yet a further aspect of the invention there is provided a method to assay and record a tissue/fluid sample from an individual comprising;

(i) applying a sample to a sample application well of an assessment device as hereindescribed;

(ii) mixing said sample with at least primary assay reagents;and

(iii) recording the data from i-ii via the recording part.

It will be apparent to one skilled in the art that this method enables the rapid processing of an applied fluid/tissue sample within minutes of application to the sample well. This will reduce erroneous assay of samples due to sample degradation during long term storage.

It is well known in the art that assay reagents comprise, and not by way of limitation, buffers, substrates, enzymes, antibodies, co-factors, intermediary metabolites, nucleic acid. It will also be apparent that there are well known in the art means to assay various factors. For example, antibody techniques using polyclonal/monoclonal antibodies to specific epitopes (e.g. drugs, hormones, steroids, tumour specific cell surface antigens, viral/bacterial antigens) . Enzyme based techniques for monitoring, for example, glucose or cholesterol in blood plasma. Many of these techniques rely on a colour change as an indication of the presence of the desired agent(s). More recently chemiluminescent and/or fluorescent detection means are available and will be applicable to the assay recording device.

According to yet a further aspect of the invention there is provided a kit comprising; an assessment device as hereindescribed, assay reagents and

optionally protective packaging for transport of the recording device to the processing facility.

It will be apparent that the recording assay device has widespread application in the diagnosis of disease. It may also have a role in clinical trials assessment of potential therapeutic agents providing a non-biased means of collecting data from treated and placebo groups to ensure a reliable assessment of drug efficacy is obtained.

An embodiment of the invention will now be described, by example only, and with reference to the following figures wherein,

Figure 1 is a diagrammatic representation of the assay part of an assessment device;

Figure 2a is a diagrammatic representation of the internal layout of an assessment device; and

Figure 2b represents a diagrammatic representation of an external view of an assessment device

Referring to figure 1, a diagrammatic representation of an assay part of the recording assay device is shown . The assay part is characterised by the presence of a selectively sized and shaped sample application well (1) which is circular in the diagram. The sample application well (1) is in fluid contact with a primary assay reagent conduit (2). The primary reagent conduit is selectively sized to facilitate the movement of sample applied to the application well(1) by capillary flow. The primary reagent conduit contains

at least some of the reagents necessary to complete a reaction with the sample applied to the sample well (1) or begin an initial reaction with the applied sample. Additionally the reagents may represent solutions used to dilute the sample and/or primary assay reagents. A single assay well (1) is shown in the diagram. However, the device may be adapted to contain multiple application wells in fluid contact with one or more primary reagent conduits.

The primary assay reagent conduit comprises filter paper, or other suitable means, impregnated with the primary assay reagents and can comprise additionally, or alternatively, any of the following alternatives;

(i) multiple channels formed in paper or other water permeable material by impregnation with polymers to form water impermeable regions;

(ii) multiple channels formed in nitrocellulose or other water permeable diagnostic or filter membrane by impregnation with wax to form water impermeable regions;

(iii) formation of strips of water permeable material within a sheet of the material by cutting regions from a sheet of the material, in order to form multiple channels;

(iv) printing (e.g. by silk screen) of a water permeable material (e.g. nitrocellulose or other material used to make diagnostic and filter membranes) in emulsion or other fluid form onto a water impermeable surface to create channels of the water permeable material;

(v) multiple water permeable channels comprised of any material and produced by any method;

(vi) a single water permeable channel or strip comprised of any material and produced by any method. In a single channel device there would be one or more detection zones;

(vii) a channel(s) of free space, within a water impermeable structure, forming a capillary in which liquid may flow by capillary action. This technique is sometimes referred to as a "capillary flow" diagnostic device. In a single channel device there would be one or more detection zones; and

(viii) other types of channel.

In use a fresh sample applied at (1) is moved via capillary action into the primary reagent conduit. The filter paper may be hydrophilic over at least part of its area to restrict and/or concentrate the flow of sample along the primary conduit (2).

The primary reagent conduit is optionally in fluid contact with a secondary reagent conduit (3) containing secondary assay reagents. The secondary reagent conduit is selectively sized to facilitate capillary flow of sample from the primary reagent conduit. Figure 1 represents a single secondary reagent conduit. In an alternative embodiment of the invention more than one secondary reagent conduit may be present containing reagents required to complete the assay. Again capillary flow will draw the sample/primary assay reagent mix into the secondary assay conduit (3) to facilitate the reaction of secondary reagents with the sample/primary assay reagent mix. A detection zone (4) is selectively positioned to interact with the reaction mixture once all components have been mixed and the assay completed. The detection zone (4) may contain substrates necessary to allow detection of the product of the assay. Alternatively, these substrates may be incorporated in

the primary and/or secondary mix. Detection may be via a colour change or other suitable means (e.g. chemiluminescence, fluorescence emission).

Two preferred detection means are readily applicable to the assessment device;

(i) recording of an electrochemical reaction by a microprocessor or other solid-state device. Amperometric and potentiometric assay detection techniques are appropriate. This is the preferred detection system, as the removable recording system can be kept from contacting physically with any of the components of the sample by means of the electrical connection between the detection zone and the recording device, thus rendering it completely safe from infectious risk on handling, figure 2; and

(ii) recording of a photometric reaction by a photographic or other light sensitive film or device. Chemiluminescence and fluoresence are appropriate. The film and detection zone can be separated by a clear water impermeable layer which will prevent the film from contacting physically with any of the components of the sample.

Additionally other detection means include;

(iii) reflectance or transmittance photometry; production of a stable dye on a surface by biochemical or chemical reaction, including ELISA;

(iv) microparticles, including polymers, metallic and non-metallic elements and other materials;

(v) soluble coloured substances, including dyes. These would be determined by a light reflectance technique(including fluorimetry) or light transmittance technique or another technique related to any specific feature of any soluble substance used; and

(vi) other assay detection systems.

The detection is recorded and stored in a microprocessor located in the recording means, not shown in figure 1. The assay part is further adapted by the provision of a waste well (5) to store excess sample/reaction mix.

Referring to Figure 2a, an alternative embodiment of an assay part is shown diagrammatically with a detachable recording part (7). The single sample application well is shown (1) in fluid connection with a plurality of conduits (6). The conduits identified in figure 2a may contain alternate assay reagents to facilitate multiple testing of variables of the applied sample. For instance, glucose, salts, hormone levels, the detection of specific epitopes via immune reaction. The plurality of conduits (6) each contain a detection zone (4), each of which is connected to a microprocessor (8) via electrical connections (7) to facilitate interrogation of the assay in the detection zone (4). The assay recording device is also provided with a test ready indicator (9) to monitor device status thereby allowing the user to readily identify when the device has completed the assay.

Referring to Figure 2b an external diagrammatic representation of an assay/recording device is shown. The outer casing (12) is manufactured from a durable material, (e.g. reinforced plastic). The recording part is easily detached from the assay part via a perforated attachment means (11). Alternatively the assay part and recording part may be selectively attached via a clip, hasp, lock, or any suitable means to facilitate the attachment or detachment of said assay part from said recording part. In use the patient applies a sample to a sample well (1) through an application port (13). When sufficient time has lapsed to allow the assay to reach an end point the

test ready indicator (9) conveys this to the user. The user can then simply detach the recording part from the assay part and send the data to a processing facility for decoding and interrogation.

The invention therefore provides for a device that operates in a stable, reliable and reproducible manner and advantageously the results of the assay are not available to a user until further, remote, processing has occurred.

CLAIMS

1. An assessment device comprising a first part adapted to undertake an assay wherein said part comprises at least one sample application well, in fluid connection with at least one primary conduit;wherein either, or both, of said well and said conduit contain material(s) for sampling a fluid sample; and a test ready indicator whereby a user can determine when a sample has been suitably assayed; and a second part which is a detachable recording device adapted to store information relating to at least to said sample after said assay has been completed and which is in data communication with said first part for storing assay results.

2. An assessment device according to Claim 1 wherein said assessment device and/or recording part is selectively sized and shaped to facilitate handling and transport of same to a processing facility.

3. An assessment device according to Claims 1 or 2 wherein said recording part is adapted to facilitate the transfer of data via electronic means.

4. An assessment device according to Claims 1-3 wherein said recording part is in retro-fit form.

5. An assessment device according to Claims 1-4 wherein said recording part is a microchip or a micro processor.

6. An assessment device according to Claims 1-5 wherein said recording part is a photographic recording means.

7. An assessment device according to Claims 1-6 wherein said assay part is characterised by multiple sample application wells.

8. An assessment device according to Claim 7 wherein at least one of said sample application wells is impregnated with material(s) for assaying a fluid sample.

9. An assessment device according to Claim 7 or 8 wherein said primary conduit contains reagents suitable for diluting said sample fluid.

10. An assessment device comprising a primary conduit according to Claims 7-9 wherein said primary conduit is suitably sized to facilitate capillary flow of said sample fluid therethrough.

11. An assessment device according to Claims 7-10 wherein said assay part is provided with at least one secondary conduit which is in fluid connection with one or more of said sample application wells.

12. An assessment device according to Claim 11 wherein said secondary conduit is suitably sized to facilitate capillary flow of said sample fluid therethrough.

13. An assessment device according to Claims 11 or 12 wherein said secondary conduit contains assay reagents.

14. An assessment device according to Claim 13 wherein said assay reagents are of a different nature to the assay reagents in the said primary conduit.

15. An assessment device according to Claim 14 wherein said assay reagents are compatible with the assay reagents of the primary conduit so as to provide, in total, for the complete and selected assaying of said

fluid sample as it flows through either or both primary and/or secondary conduits.

16. An assessment device according to Claims 1-15 wherein said assessment device includes at least one control or calibration means.

17. An assessment device according to Claims 1-16 wherein said assay part is provided with at least one detection zone to facilitate detection of the product(s) and/or responses of an assay.

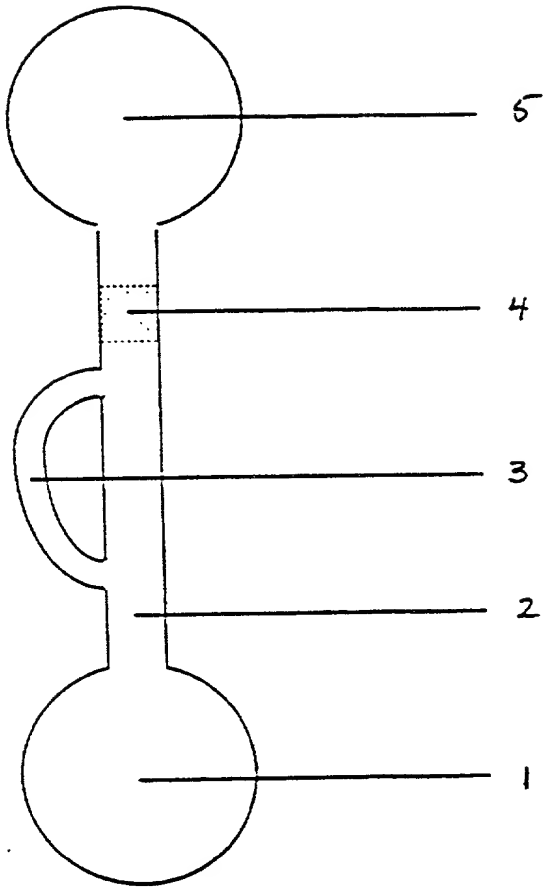
18. A method to assay and record a tissue/fluid sample comprising;

i) applying a sample to at least one sample application well of an assessment device according to Claims 1-17;

ii) mixing said sample with at least primary assay reagents; and

iii) recording the data from i)-ii) via the recording part.

19. A kit comprising an assessment device according to any preceding claim comprising an assessment device, assay reagents and, optionally, protective packaging for transport of the recording device to a processing facility.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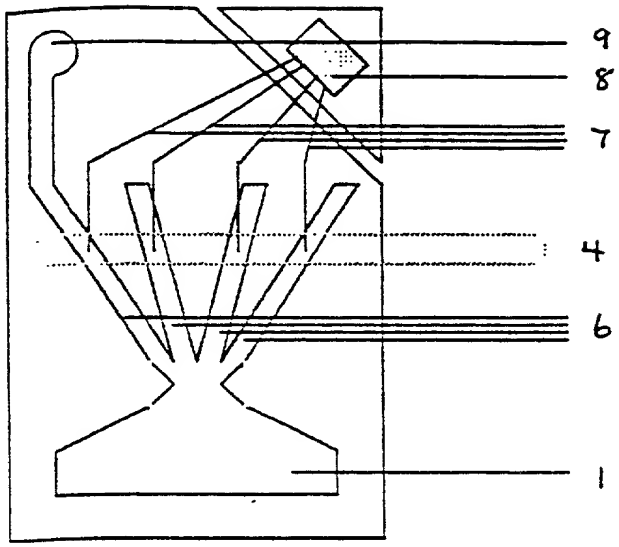
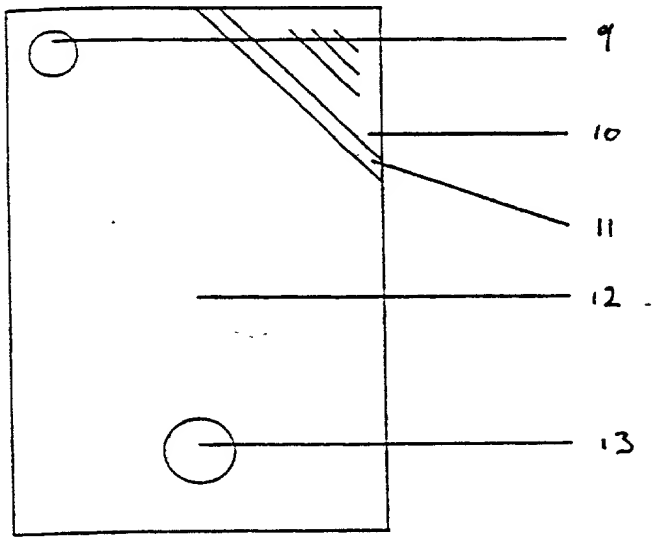
1

EXAMPLE - INTERNAL LAYOUT



EXAMPLE - EXTERNAL VIEW



Attorney Docket No.: 2426-1-001

DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below under my name

I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

RECORDING ASSAY DEVICE

the Specification of which

[X] is attached hereto

[X] was filed on 18 March 1998

as International Application No. PCT/GB98/00815

I hereby state that I have reviewed and understand the contents of the above-identified Specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, 1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 (a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or §365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

PRIOR FOREIGN FILED APPLICATION(S)

APPLICATION NUMBER	COUNTRY	(MONTH/DAY/YYYY)	PRIORITY CLAIMED
9705667.5	Great Britain	March 19, 1997	YES

I hereby claim the benefit under Title 35, United States Code §119(e) of any United States provisional application(s) listed below.

APPLICATION NUMBER(S)	FILING DATE (MM/DD/YYYY)

Attorney Docket No.: 2426-1-001

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s), or §365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of Title 35, United States Code §112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. Parent Application No.	PCT Parent Number	Parent Filing (MM/DD/YYYY)	Parent Patent Number (if applicable)

The undersigned hereby authorizes the U.S. attorney or agent named herein to accept and follow instructions from Markgraaf Patents as to any action to be taken in the Patent and Trademark Office regarding this application without direct communication between the U.S. attorney or agent and the undersigned. In the event of a change in the persons from whom instructions may be taken, the U.S. attorney or agent named herein will be so notified by the undersigned.

I hereby appoint as my attorneys or agents the following persons: Jack Matalon, (Attorney, Registration No. 22,441); Stefan J. Klauber (Attorney, Registration No. 22,604); David A. Jackson (Attorney, Registration No. 26,742); Michael D. Davis (Attorney, Registration No. 39,161); Christine E. Dietzel (Agent, Registration No. 37,309); Donald J. Cox (Attorney, Registration No. 37,804); and Michael A. Yamin (Agent, Registration No. 44,414), said attorneys or agents with full power of substitution and revocation to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

Please address all correspondence regarding this application to:

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

1-00 FULL NAME OF FIRST OR SOLE INVENTOR: JAMES RICHARD JACKSON

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SIGNATURE OF INVENTOR James Jackson

DATE 17/Sept/99

TOTAL P.05